BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**9/15/2016**
LAST REVIEW DATE:	**5/19/2022**
LAST CRITERIA REVISION DATE:	**5/19/2022**
ARCHIVE DATE:	

OFF-LABEL USE OF NON-CANCER MEDICATIONS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** An exception request for **Off-Label Use of a *non-cancer* medication** may be considered ***medically necessary*** and will be approved with **ALL** of the following criteria met:

  1. The drug has been approved by the FDA for at least **ONE** other indication

  2. Provider submits a diagnosis and treatment plan that includes the rationale for the exception for off-label use

  3. Failure, contraindication, or intolerance to **at least 2 or more** other FDA-approved medications that are on the formulary

  4. Evidence that supports the off-label use is recognized as safe and effective and is supported by **ONE** of the nationally recognized compendia, guidelines, or literature:
     a. American Hospital Formulary Service Clinical Drug Information with narrative text of "supportive"
     b. IBM Micromedex DrugDex compendium that meet **ALL** of the following:
        i. Strength of Recommendation of Class I or IIa or IIb
        ii. Strength of Evidence Category A or B
        iii. Strength of Efficacy Class I or IIa (evidence favors efficacy)
     c. Elsevier Gold Standard's Clinical Pharmacology compendium with narrative text of "supportive"
     d. Wolters Kluwer Lexi-Drugs with use listed as "off-label, evidence level A"
     e. Other authoritative reference as identified by the Secretary of the United States Department of Human Health Services
     f. At least **TWO** articles from major peer reviewed professional medical journals that have recognized, based on scientific or medical criteria, the safety and effectiveness for the exception

  5. There are no contraindications for use of the requested drug

  6. There are no significant interacting drugs

  7. There are no benefit or contract exclusions that apply

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request): Off-Label Use of a non-cancer medication** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
        ii. Documented evidence of efficacy, disease stability and/or improvement

  2. Individual has been adherent with the medication

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3. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use

4. There are no significant interacting drugs

5. There are no benefit or contract exclusions that apply

Renewal duration: 12 months

- **Criteria when use is considered experimental or investigational:** The exception request is considered ***experimental or investigational*** and will not be covered when any **one or more** of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement outside the investigational setting

  These indications include, but are not limited to:
  - Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, when appropriate.

Description:

For FDA approved indication(s), also known as labeled indication(s), the FDA has reviewed and approved the medication for the specified use(s) for marketing based on adequate, well-controlled clinical trials, which have documented safety and effectiveness. The use of an FDA approved medication for conditions, indications or in circumstances other than those approved by the FDA is known as “off-label use” (also referred to as unapproved use or unlabeled use). Unapproved or unlabeled uses include a variety of situations ranging from completely unstudied uses to scientifically investigated uses where the manufacturer has not asked the FDA for formal approval.

Off-label use of medications that have previously received FDA approval for marketing may be reviewed in any of the following ways: for medical necessity and/or investigational uses; during a review of a medication that requires prior authorization; during review of a medication due a non-formulary request for coverage; or during a review for any other prescription limitations.

An approved NDA (New Drug Application), ANDA (Abbreviated New Drug Application), or BLA (Biologic License Application) is considered final FDA-marketing approval for the purposes of this policy.

In certain instances, scientific evidence may support using a drug to treat a disease even if the drugs FDA approved label does not include those clinical conditions. In these circumstances, a compendia or scientific peer-reviewed literature specific for the indication in question may recommend uses beyond those included in the FDA approved labels. A compendium is a comprehensive listing of FDA approved drugs and biologics. Compendia

include a summary of how each drug works in the body, as well as information for health care practitioners about proper dosing and whether the drug is recommended or endorsed for use in treating a specific disease.